

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Pettersson et al.
Serial No: 10/531,598
Filed: 25 November 2005
For: Gastric Acid Secretion Inhibiting Composition

Group Art Unit: 1618
Examiner: M.P.Young

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

TRANSMITTAL OF INFORMATION DISCLOSURE STATEMENT BEFORE MAILING DATE
OF EITHER A FINAL ACTION OR NOTICE OF ALLOWANCE (37 CFR 1.97(c))

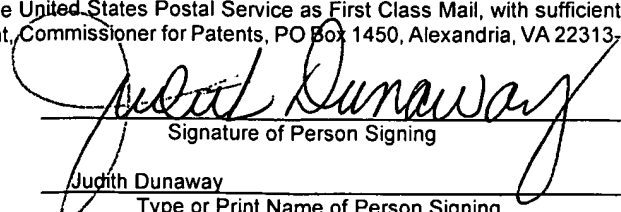
- NOTE: "An information disclosure statement shall be considered by the Office if filed ... before the mailing date of either (1) a final action under S 1.113 or (2) a notice of allowance under S 1.311, whichever occurs first, provided the statement is accompanied by either a certification as specified in paragraph (e) of this section or the fee set forth in S 1.17(p)." 37 CFR 1.97(c).
- NOTE: "If a final action or notice of allowance is mailed in an application and later withdrawn, the application will be considered as not having had a final action or notice of allowance mailed for purposes of considering an information disclosure statement." Notice of April 20, 1992 (1138 O.G. 37-41, 39).
- NOTE: "If information submitted during the period set forth in 37 CFR 1.97(c) with a certification is used in a new ground of rejection on unamended claims, the next Office action will not be made final since in this situation it is clear that applicant has submitted the information to the office promptly after it has become known and the information is being submitted prior to a final determination on patentability by the Office. However, the information submitted with a certification can be used in a new ground of rejection and the next Office action made final, [i]f the new ground of rejection was necessitated by amendment of the application by applicant. Where the information is submitted during this period with a fee, the examiner may use the information submitted, e.g., printed publication or evidence of public use, and make the next Office action final whether or not the claims have been amended, provided that no other new ground of rejection which was not necessitated by amendment to the claims is introduced by the examiner. See MPEP 706.07(a). If a new ground of rejection is introduced that is neither necessitated by an amendment to the claims nor based on the information submitted with the fee set forth in 37 CFR 1.17(p), the Office action shall not be made final." Notice of April 20, 1992 (1138 O.G. 37-41, 39).

TIME OF TRANSMITTAL OF ACCOMPANYING INFORMATION
DISCLOSURE STATEMENT

1. The information disclosure statement transmitted herewith is being filed AFTER THREE MONTHS OF THE FILING DATE OF THIS NATIONAL APPLICATION OR THE DATE OF ENTRY OF THE NATIONAL STAGE AS SET FORTH IN S 1.491 IN AN INTERNATIONAL APPLICATION OR AFTER THE MAILING DATE OF THE FIRST OFFICE ACTION ON THE MERITS, WHICHEVER EVENT OCCURRED LAST BUT BEFORE THE MAILING DATE OF EITHER:
 - (1) a final action under § 1.113 or
 - (2) a notice of allowance under § 1.311,
whichever occurs first.

CERTIFICATE OF MAILING (37 CFR 1.8a)

I hereby certify that this correspondence is being deposited with the United States Postal Service as First Class Mail, with sufficient postage, in an envelope addressed as follows: Mail Stop Amendment, Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450, on 27 April 2009


Signature of Person Signing

Judith Dunaway

Type or Print Name of Person Signing

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CERTIFICATION OR FEE

2. Accompanying this transmittal is
(check either A or B below)
- A. ☐ a certification as specified in 37 CFR 1.97(e)
OR
- B. ☒ the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under S 1.97(c). (\$180.00).

FEE PAYMENT

(complete this item, if applicable)

3. Applicant elects the option to pay the fee set forth in 37 CFR 1.17(p) for submission of an information disclosure statement under S 1.97(c) (\$180.00).

Fee due \$ 180.00

METHOD OF PAYMENT OF FEE

4. ☒ Attached is check in the amount of \$ 180.00
- ☐ Charge Account No. in the amount of \$
A duplicate of this request is attached.

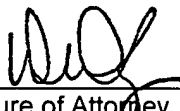
The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* prior art reference against the claims of the present application.

If any additional fees are due, please charge Account No. 06-2360.

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Patent

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Pettersson et al

Attorney Docket No.: 9404.20834

Serial No.: 10/531,598

Examiner: Micah-Paul Young

Filed: November 25, 2005

Group Art Unit: 1618

Title: Gastric Acid Secretion Inhibition Composition



SUBMISSION OF
DECLARATION OF NIMISH VAKIL, M.D., FACP, FACG
AND
INFORMATION DISCLOSURE STATEMENTS
AND
REQUEST FOR INTERVIEW

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

INTRODUCTORY COMMENTS

A Request for Continued Examination and Amendment B have been filed in response to the Office Action mailed February 7, 2008.

Applicant submits the Declaration of Nimish Vakil, M.D., FACP, FACG, with Attachments 1 to 14. An Information Disclosure Statement listing the Attachments also accompanies this submission.

Additional Information Disclosure Statements also accompany this submission. The Information Disclosure Statements list the Office Actions and Interview Summaries issued in related co-pending Applications Serial Nos. 10/475,254 and 11/822,502 (Examiner S. Tran, Art Unit 1615). Copies of the Office Actions and Interview Summaries listed are also attached.

A Request for an Interview also accompanies this submission.

REMARKS

On April 25, 2008, Applicant was granted a personal interview with the Examiner and his Supervisor, whose time and attention are appreciated. At the interview, applicant submitted arguments to establish the level of skill in the art at the time of filing, and that the prevailing knowledge of the art would teach away from the combination of a PPI (a proton pump inhibitor) and a H2RA (H2 receptor antagonist). At the conclusion of the interview, the Examiner suggested the inclusion of the specific PPI and H2RA into the base claim. The Examiner also suggested the submission of Declarations "with strong language" supporting the level of skill in the art.

On March 9, 2009, Applicant filed a Request for Continued Examination and Amendment B to focus, simplify, and advance prosecution in accordance with the Examiner's suggestions.

As also suggested by the Examiner, Applicant submits the Declaration of Nimish Vakil, M.D., FACP, FACG. Dr. Vakil is a certified, practicing physician, specializing in internal medicine and, in particular, in gastroenterology. Besides being a certified physician who has treated patients since 1985, he has been a professor of medicine on the faculties of the University of Texas, University of Rochester, University of Wisconsin, University of Wisconsin Medical School, and the Marquette University College of Health Sciences. An area of personal and professional interest, experience, and expertise for Dr. Vakil as a physician and educator within the field of gastroenterology is in the treatment of the disease called gastro-esophageal reflux disease (GERD). He has studied the medical literature and himself written extensively on the subject, having, since 2000, authored or co-authored over 30 publications directed to the pathophysiology, diagnosis, and management of GERD. Dr. Vakil's personal and professional interest, experience, and expertise in this area are recognized by his colleagues. For example, in 2002, he was among twenty-eight participants from ten countries who were selected on the basis of their interest, experience, and expertise in the treatment of GERD to attend a two day international multidisciplinary workshop to critically review the data regarding the reliability, processes, and priorities for symptom evaluation in GERD patients. In 2002, Dr. Vakil was also honored by the selection as chairman of an international consensus group of experts and family physicians selected on the basis of their "demonstrated knowledge/expertise in GERD by publication/research or participation in national or regional GERD consensus guidelines or an interest in guideline development and dissemination." Dr. Vakil was recently honored to be included among a faculty panel of eight physicians in a recent

continuing medical education program sponsored by the American Gastroenterological Association to address "Improving the Management of GERD: Evidence-Based Therapeutic Strategies." He and his fellow panel members were identified as "practicing experts devoted to the investigation of and treatment of GERD and GERD-related illness."

In his Declaration, Dr. Vakil comments on the invention defined in the pending claims from the perspective of a person of considerable skill, experience, and expertise in the field of gastroenterology and related pharmacology. At first skeptical about the scientific and medical efficacy of the invention, Dr. Vakil states in his Declaration (*inter alia*):

"It is my opinion now that the Invention qualifies as a scientific and clinical 'breakthrough' in the sense that it changes the way that my colleagues and I in the field had, prior to the Invention, thought about the pharmacology of drugs like H2RA's and PPI's and their physiologic effects on acid secretion in the stomach in the treatment of GERD. Before the Invention, my colleagues and I believed that it was never appropriate to co-administer a H2RA and PPI simultaneously or concomitantly. Further, at that time, my colleagues and I were confident that we had the requisite logical, scientific, and medical reasons to back-up our beliefs in this respect. The Invention has challenged us to rethink our beliefs on the subject." (§ 12)

An Interview Request also accompanies the submission of the declaration. Applicant believes a personal interview prior to the examination of the amended claims would be helpful to the Examiner and his Supervisor, and would expedite prosecution of this application. Dr. Vakil plans to attend the Interview to answer any questions that the Examiner and/or his Supervisor might have. Applicant will follow up with a telephone call to the Examiner to schedule a convenient date and time for the Interview.

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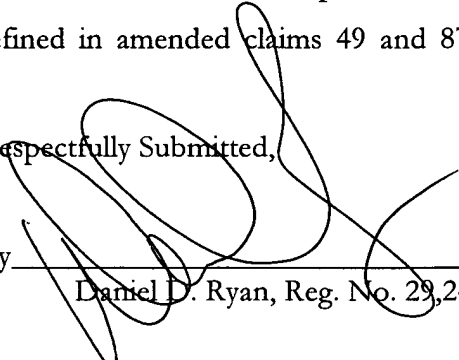
Submission of Declaration of Nimish Vakil, M.D., FACP, FACG; Information Disclosure Statements; and Request for Interview

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Applicant believes that the record establishes that, taking into account the scope and content of the prior art, the differences between the claim invention and the prior art, and the level of ordinary skill in the art, the subject matter defined in amended claims 49 and 87 to 117 is not encompassed by the prior art.

Respectfully Submitted,

By


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